

## SPECIALTY GUIDELINE MANAGEMENT

### AVEED (testosterone undecanoate injection)

#### POLICY

##### I. INDICATION

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

###### A. FDA-Approved Indications

Aveed is indicated for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone.

1. Primary hypogonadism (congenital or acquired): testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchiectomy, Klinefelter's syndrome, chemotherapy, or toxic damage from alcohol or heavy metals. These men usually have low serum testosterone concentrations and gonadotropins (follicle-stimulating hormone [FSH], luteinizing hormone [LH]) above the normal range.
2. Hypogonadotropic hypogonadism (congenital or acquired): gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency, or pituitary-hypothalamic injury from tumors, trauma, or radiation. These men have low testosterone serum concentrations but have gonadotropins in the normal or low range.

Aveed should only be used in patients who require testosterone replacement therapy and in whom the benefits of the product outweigh the serious risks of pulmonary oil microembolism and anaphylaxis.

Limitations of use:

- Safety and efficacy of Aveed in men with "age-related hypogonadism" (also referred to as "late-onset hypogonadism") have not been established.
- Safety and efficacy of Aveed in males less than 18 years old have not been established.

All other indications are considered experimental/investigational and not medically necessary.

##### II. REQUIRED DOCUMENTATION

The following information is necessary to initiate the prior authorization review: For primary hypogonadism or hypogonadotropic hypogonadism, pretreatment morning serum total testosterone concentrations

##### III. EXCLUSIONS

Coverage will not be provided for members with any of the following exclusions: Use for age-related hypogonadism or late-onset hypogonadism

Reference number(s)
2432-A, 3918-A

#### IV. CRITERIA FOR INITIAL APPROVAL

##### A. Primary hypogonadism or hypogonadotropic hypogonadism

Authorization of 12 months may be granted for treatment of primary hypogonadism or hypogonadotropic hypogonadism when all of the following criteria are met:

1. Member is a biological male or a person that self identifies as male.
2. Member is at least 18 years of age.
3. Member has at least two confirmed low morning serum total testosterone concentrations based on the reference laboratory range or current practice guidelines.

#### V. CONTINUATION OF THERAPY

##### A. Primary hypogonadism or hypogonadotropic hypogonadism

For members requesting authorization for continuation of therapy with primary hypogonadism or hypogonadotropic hypogonadism who are not currently receiving Aveed therapy through samples or a manufacturer's patient assistance program, authorization of 12 months may be granted if the member meets criteria IV.1 and IV.2 above. All other members (including new members) must meet all initial authorization criteria.

#### VI. REFERENCES

1. Aveed [package insert]. Malvern, PA: Endo Pharmaceuticals Solutions Inc.; October 2019.
2. Bhasin S, Brito JP, Cunningham GR, et al. Testosterone Therapy in Men with Hypogonadism: An Endocrine Society Clinical Practice Guideline. *J Clin Endocrinol Metab.* 2018;103(5):1715-1744.
3. IBM Micromedex® DRUGDEX® (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. Available at: <https://www.micromedexsolutions.com/> (cited: February 13, 2020).